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David G. Rosenbaum
ROSENBAUM & ASSOCIATES, P.C
Suite#380
650 Dundee Road
Northbrook, IL 60062

EXAMINER	
PRONE, CHRISTOPHER D	

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHRISTOPHER T. BOYLE, DENES MARTON,
and CHRISTOPHER E. BANAS

Appeal 2008-5417[1]
Application 10/672,695
Technology Center 3700

Decided: March 31, 2009[2]

Before TONI R. SCHEINER, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The real party in interest is Advanced Bio Prosthetic Surfaces, L.L.C.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

"[T]he present invention provides an implantable graft that includes a microporous thin film covering comprised of a metallic . . . material and an underlying structural support made of a metallic . . . material" (Spec. 3: 22-24). "The microporous thin film covering is physically attached to the underlying structural support, preferably by welding, suturing, or other commonly known methods of attachment at particular interfacial points" (*id.* at 3: 28-30). "The underlying structural support, without the microporous thin film covering, is similar to implantable devices known as . . . 'stents'" (*id.* at 4: 5-6).

Claims 1, 18, and 29 are representative of the subject matter on appeal:

1. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering having a pattern of microporous openings passing therethrough;

(b) a metal structural support element having at least one affixation member, a pattern of openings passing through the metal structural support element and underlying the microporous metal thin film covering comprised of a metallic material; and

(c) wherein the metal structural support element is attached to the microporous metal thin film covering only at the at least one affixation member.

18. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of a shape memory alloy having an austenite phase transition start temperature greater than 37° C; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of cylindrical elements and interconnecting members joining adjacent cylindrical elements, the structural support element further comprised of a shape memory alloy having an austenite phase transition start temperature less than 0° C;

(c) the structural support element being attached to the microporous metal thin film covering at at least one point of attachment between the microporous metal thin film covering and the structural support element.

29. An implantable endoluminal graft, comprising:

(a) a microporous metal thin film covering comprised of nitinol; and

(b) a structural support element underlying the microporous covering comprised of at least a pair of undulating cylindrical elements having a plurality of peaks and valleys and interconnecting members joining adjacent cylindrical elements at either the peaks or the valleys and having at least one projection extending longitudinally from a terminal cylindrical element, the structural support element being comprised of nitinol,

(c) the structural support element being joined to the microporous metal thin film covering at the at least one projection.

The Examiner relies on the following evidence:

Wright et al.	US 6,585,764 B2	Jul. 1, 2003
Burmeister et al.	CA 2 512 311 A1	Nov. 30, 1995

The Examiner rejected claims 1-6, 8-12, 15, 18-24, 26, 27, 29-31, 34, and 35 under 35 U.S.C. § 103(a) as unpatentable over Burmeister and Wright.

We affirm-in-part.

THE ISSUES

With respect to claim 1 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering, with microporous openings passing therethrough, attached to an underlying metal structural support through an affixation member would have been obvious over the combined teachings of Burmeister and Wright.

With respect to claim 18 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support through at least one point of attachment would have been obvious over the combined teachings of Burmeister and Wright.

Finally, with respect to claim 29 and its dependent claims, the issue raised by this appeal is whether the Examiner has established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support through at least one projection would have been obvious over the combined teachings of Burmeister and Wright.

FINDINGS OF FACT

The Invention

FF1 Independent claim 1 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering having "microporous openings passing therethrough," and an underlying metal structural support element "having at least one affixation

member," wherein the structural support element is attached to the microporous covering "only at the at least one affixation member."

FF2 Independent claim 18 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering and a structural support element, wherein there is "at least one point of attachment" between the microporous covering and the structural support element. Claim 18 does not recite that the microporous metal thin film has "microporous openings passing therethrough."

FF3 Independent claim 29 is directed, in pertinent part, to an implantable endoluminal graft comprising a microporous metal thin film covering and an underlying structural support element "having at least one projection extending longitudinally from a terminal cylindrical element," "the structural support element being joined to the microporous . . . covering at the at least one projection." Claim 29 does not recite that the microporous metal thin film has "microporous openings passing therethrough."

FF4 "A principal . . . example of the present invention . . . [is an] endovascular stent[ ]" (Spec. 1: 29-30), and the underlying structural support element of the graft/stent "provides the necessary structural component to support an endoluminal wall" (*id.* at 3: 18).

FF5 The Specification describes an "alternative embodiment" in which the microporous metal thin film covering overlying the structural support of the stent/graft has a "plurality of openings" (Spec. 21: 23), and the openings "can have a varying size . . . so that cellular migration occurs

thorough each opening" (*id.* at 21: 20-22), "permitting transmural endothelialization"[3] (*id.* at 21: 28) of the graft.

Burmeister

FF6 Burmeister describes a stent "comprised of at least one . . . portion which exhibits a tendency to self-expand the device to an expanded size and at least one other . . . portion which is deformable so as to allow an external force . . . to further expand it to a final, larger desired expanded size" (Burmeister 3: 5-10). "[T]he portions may be discrete or merely different phases of an alloy" (*id.* at 3: 18-19).

FF7 Figure 3 of Burmeister "is an end view of a layered stent having two discrete components" (Burmeister 4: 6-7). Figure 3 is reproduced below:

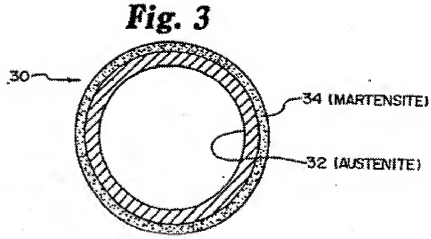


Figure 3 depicts a layered stent with "martensitic and austenitic phase characteristics of shape memory alloy(s) in the two discrete components 32

[3] Transmural: an adjective defined as "passing or administered through an anatomical wall; *also* "involving the whole thickness of a wall" (http://dictionary.reference.com/browse/transmural (accessed: February 13, 2009)).

and 34" (Burmeister 9: 23-24). "[T]he austenitic portion [may be made] with any standard metallurgical technique and . . . the martensitic portion [may be vapor deposited] on its surface. Other manufacturing techniques such as diffusion bonding, welding, ion beam deposition, and various others will be apparent" (*id.* at 9: 3-7).

FF8 The Examiner finds that Burmeister's component 32 is a structural support element, and component 34 is a thin film covering (Ans. 4), and that "the two layers . . . are completely bonded together throughout their surface areas" and "[t]his intersection of the two members is considered to be the affixation member" or "point of attachment" required by the claims (*id.* at 6).

FF9 The Examiner finds that "Burmeister does not disclose that the thin film covering comprises a microporous surface" (Ans. 4).

FF10 Wright describes a stent "whose body has been modified to contain micropores or channels" that act as reservoirs for a therapeutic agent which will be delivered to the vessel wall (i.e., to the outside, or abluminal side of the stent) (Wright, col. 6, ll. 49-50; col. 3, ll. 51-55).

FF11 Wright's Figures 1a and 1b, reproduced below, show top and section views of a stent containing reservoirs:

FIG. 1

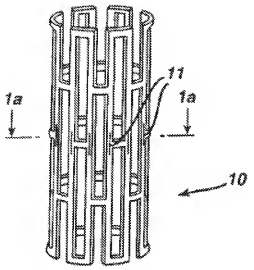
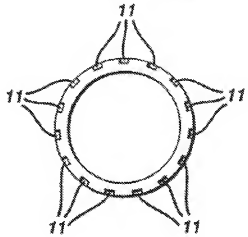


FIG. 1a



Figures 1a and 1b depict stent struts containing drug reservoirs (11).

FF12 According to the Examiner, Wright's implantable stent comprises "a microporous outer surface" (Ans. 4) which "qualif[ies] as an equivalent structure" (*id.* at 6) to the microporous metal thin film covering required by the present claims.

PRINCIPLES OF LAW

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

ANALYSIS

According to the Examiner, Burmeister's stent has "2 distinct layers clearly shown in figure 3" (Ans. 5). "[T]he outer layer 34 [is] a thin metal film and the[ ] inner layer 32 [is] a support layer" (*id.*). According to the Examiner, "the two layers of Burmeister are completely bonded together throughout their surface areas" and "[t]his intersection of the two members is considered to be the affixation member" or "point of attachment" required by the claims (*id.* at 6).

The Examiner acknowledges that "Burmeister does not disclose that the thin film covering [32] comprises a microporous surface" (Ans. 4), but concludes that it would have been obvious to "combine the microporous outer surface as taught by Wright with the implant of Burmeister in order to deliver a drug to the implant site" (*id.* at 5).

Appellants contend that "the claims on appeal require an actual element described as an 'affixation member', a 'point of attachment', or a 'projection,'" (App. Br. 12), which accomplishes "the physical joining of the microporous thin film covering and the structural support element" (*id.* at 13). Appellants contend that the "interface between a martensitic layer 34 and an austenitic layer 32" in Burmeister's bi-layered stent is merely where "the two layers of the Burmeister stent touch each other" (*id.* at 11), and "does not constitute an affixation element" (*id.* at 12).

We agree with Appellants that independent claims 1 and 29, at least, require an "actual element" (App. Br. 12), i.e., an "affixation member" or a "projection" joining the covering and the structural support element, and that this limitation is not met by Burmeister's two adjacent layers. Independent claim 18, however, does not specify any particular element joining the

covering and the support layer, but merely requires that the covering and support element are attached at "at least one point of attachment." We agree with the Examiner that Burmeister's layers are attached at "at least one point of attachment."

Nevertheless, Appellants additionally contend that the "microporous metal thin film covering" required by the claims has micropores "passing therethrough" (App. Br. 7), that is, it has "holes or openings passing through the thickness of the metal thin film covering" (*id.*). Appellants contend that "[t]he 'microporous metal thin film covering having a pattern of microporous openings passing therethrough' represents a key feature" of the invention (*id.* at 9).

Appellants acknowledge that "Wright does use the term 'micropores,'" but contend that Wright's micropores "are, in fact, reservoirs or depots, and are not actual holes passing through a thin film covering" (*id.* at 7), thus, the surface of Wright's stent "do[es] not correspond to the 'microporous metal thin film covering having a pattern of microporous openings passing therethrough' as recited in the instant claims" (*id.*). Appellants contend that "the Examiner's combination of Burmeister and Wright would not be capable of achieving effective endothelialization because such a stent would not have microporous openings that traverse the metal thin film covering . . . [and] cell migration from the abluminal surface to the luminal surface would be completely obstructed" (*id.* at 10).

Wright uses the terms "micro-pores" and "channels" in describing the drug reservoirs in his stents, but it is clear, especially from Wright's Figure 1b, that the micropores or channels do not traverse the thickness of the stent strut, but are actually wells or grooves in the strut (FF10, 11).

Therefore, we agree with Appellants that even if one were to combine Wright with Burmeister, the resultant stent/graft would not have "a microporous metal thin film covering having . . . microporous openings passing therethrough" as required by claim 1 (and its dependent claims 2-6, 8-12, and 15).

However, unlike claim 1, independent claims 18 and 29 do not recite that the microporous metal thin film has "microporous openings passing therethrough" (FF2, FF3), nor do they require passages permitting cellular migration from one side of the film to the other. Nor does the Specification explicitly define the term "microporous" as requiring openings that go all the way through the metal thin film. Appellants point to page 21 of the Specification in support of their contention that the claims require "openings passing therethrough," but page 21 merely describes an "alternative embodiment" that permits transmural endothelialization (FF5).

Appellants further contend that the Specification provides a definition through "co-pending, commonly assigned U.S. Patent Applications S.N. 10/135,316 and 10/135,626, . . . both of which are hereby expressly incorporated by reference as describing the microporous thin film covering" (Reply Br. 2 (quoting the present Specification at paragraph 10)). However, the applications refer to, but do not define, "microperforations," and all of the passages pointed to by Appellants qualify the term as "passing through the film" or "passing through the graft" (Reply Br. 2-4). Unlike present claim 1, which specifies that the microporous metal thin film has "microporous openings passing therethrough" (FF1), claims 18 and 29 do not include this, or similar qualifying language, and are therefore broader than claim 1(FF2, FF3).

Wright describes a stent with "micropores" (FF10), and the present Specification does not define the term in a way that distinguishes the "microporous metal thin film" of claims 18 and 29 from Wright's stent "whose body has been modified to contain micropores" (FF10). Therefore, we agree with the Examiner that Wright's implantable stent comprises "a microporous outer surface" (Ans. 4) which "qualif[ies] as an equivalent structure" (*id.* at 6) to the microporous metal thin film covering (FF12) required by claims 18 and 29, and their dependent claims.

In summary, claims 1-6, 8-12, and 15 require a "microporous metal thin film covering having . . . microporous openings passing therethrough," a feature neither taught nor suggested by Burmeister or Wright. In addition, claims 1-6, 8-12, 15, 29-31, 34, and 35 require an "actual element," i.e., an "affixation member" or a "projection" joining the covering and the structural support element, yet another feature neither taught nor suggested by Burmeister or Wright. Claims 18-24, 26, and 27 do not require either of these features, and we agree with the Examiner that the limitations of these claims are suggested by the combined disclosures of Burmeister and Wright.

CONCLUSIONS OF LAW

With respect to claims 1-6, 8-12, and 15, the Examiner has not established that an implantable endoluminal graft comprising a microporous metal thin film covering, with microporous openings passing therethrough, attached to an underlying metal structural support through an affixation member would have been obvious over the combined teachings of Burmeister and Wright.

With respect to claims 18-24, 26, and 27, the Examiner has established that an implantable endoluminal graft comprising a microporous

metal thin film covering attached to an underlying metal structural support through at least one point of attachment would have been obvious over the combined teachings of Burmeister and Wright.

Finally, with respect to claims 29-31, 34, and 35, the Examiner has not established that an implantable endoluminal graft comprising a microporous metal thin film covering attached to an underlying metal structural support at at least one projection would have been obvious over the combined teachings of Burmeister and Wright.

Accordingly, the rejection of the claims under 35 U.S.C. § 103(a) as unpatentable over Burmeister and Wright is REVERSED with respect to claims 1-6, 8-12, 15, 29-31, 34, and 35, but AFFIRMED with respect to claims 18-24, 26, and 27.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED-IN-PART

LP

DAVID G. ROSENBAUM
ROSENBAUM & ASSOCIATES, P.C
SUITE#380
650 DUNDEE ROAD
NORTHBROOK IL 60062